DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 13, 2015

3-D Matrix Incorporated
% Ms. Denise Gottfried
TekTeam, LLC
2225 East Bayshore Road, Suite #231
Palo Alto, California 94303

Re: K143058
Trade/Device Name: PuraDerm Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 13, 2015
Received: January 14, 2015

Dear Ms. Gottfried:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143058

Device Name
PuraDerm Gel

Indications for Use *(Describe)*
OTC:
PuraDerm is used for the management of minor cuts, abrasions, minor wounds and minor burns (1st degree burns).

Rx:
Under the supervision of a health care professional PuraDerm is used for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

## 1. Sponsor Information

Applicant Name/Contact: 3-D Matrix, Inc.
Dr. Lisa Spirio
Chief Scientific Officer
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Waltham, MA 02451

Official Correspondent,
Regulatory Contact: Denise Gottfried
President & CEO, TekTeam
Regulatory Consultant to 3-D Matrix, Inc.
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Fax: 1-866-941-6602

Date Prepared: October 22, 2014, revised February 9, 2015

## 2. Device Name and Classification

| | |
|---|---|
| Trade Name: | PuraDerm™ Gel |
| Common or Usual Name: | Wound Dressing |
| Classification Name: | Dressing, Unclassified device |
| Product Code: | FRO |

## 3. Predicate Devices

Primary Predicate: DuoDerm® Hydroactive® Gel (ConvaTec); K973806

Secondary Predicate: Woun'Dres® Collagen Hydrogel (Coloplast); K991202

## 4. Device Description

PuraDerm™ Gel is a sterile gel composed of a synthetic peptide and sterile water for injection. It is provided as a prefilled syringe (2.5% peptide content) ready for use as a wound dressing with or without the optional sterile application nozzle. PuraDerm forms a moist wound environment that is supportive of the healing process and allows non-traumatic removal of the secondary dressing without damaging newly formed tissue.

PuraDerm is completely non-animal and non-plant derived, and contains no preservatives that might present a risk of allergic reaction or skin irritation.

Exposure to physiological fluids such as blood causes the peptide solution to quickly form a transparent gel without expansion in volume. PuraDerm can be easily rinsed away by gently flushing the wound with sterile saline, without causing trauma to the underlying wound.

## 5. Intended Use

OTC:
PuraDerm is used for the management of minor cuts, minor abrasions, minor wounds and minor burns (1$^{st}$ degree burns).

Rx:
Under the supervision of a health care professional PuraDerm is used for the management of partial and full-thickness wounds, such as pressure ulcers, leg ulcers, diabetic ulcers, and surgical wounds.

## 6. Comparison to Predicate Devices

PuraDerm is similar in presentation, function, and indication for use and intended use to other wound dressings, including DuoDerm® Hydroactive® Gel (ConvaTec), K973806 and Woun'Dres® Collagen Hydrogel (Coloplast), K991202.

PuraDerm is composed of a non-animal derived peptide solution in sterile water (Water for Injection, USP). Water is the majority component of PuraDerm. DuoDerm is composed of natural hydrocolloids (pectin, sodium carboxymethylcellulose) in a viscous vehicle. Woun'Dres is composed of collagen, along with skin protectants and mild preservative, presented as an amorphous gel. All three products are clear gels that are designed for the hydration and management of partial and full thickness wounds, such as pressure sores, leg ulcers, and diabetic ulcers. For the intended use of these devices, the material composition of each device does not affect the validity of the substantial equivalence determination.

## 7. Performance Data

Substantial equivalence evaluation of PuraDerm and DuoDERM was supported by non-clinical performance including *in vivo* performance testing in an established porcine wound healing model; and biocompatibility testing, as per ISO 10993-1 and the FDA Blue Book memorandum #95-1 and consistent with FDA Guidance, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The study design included DuoDerm as the control device, as DuoDerm (pectin, sodium carboxymethylcellulose in a viscous vehicle) is the predicate device to both PuraDerm and Woun'Dres and was determined to be substantially equivalent to Woun'Dres in accordance with the pre-market notification process and SE determination.

## 8. Statement of Substantial Equivalence

PuraDerm is substantially equivalent in presentation, function, indications for use and intended use to the DuoDerm® Hydroactive® Gel (ConvaTec) and Woun'Dres® Collagen Hydrogel (Coloplast) predicate devices. All three devices are clear, odorless gels which have water as the primary component for hydrating external wounds. Benchtop and animal testing have demonstrated that PuraDerm is as safe, as effective, and performs as well as the proposed predicate(s) for the proposed indications for use and intended use. A large animal safety and performance study has been conducted comparing DuoDERM to PuraDerm and results

demonstrate that PuraDerm is as safe, as effective, and performs as well as the predicate device for the intended use. The hydrating material properties of PuraDerm that support its intended use are substantially equivalent to that of both DuoDerm and Woun'Dres. In conclusion, the evaluation of the PuraDerm Gel has not raised any additional concerns regarding safety and effectiveness and has therefore been determined to be substantially equivalent to its predicate device(s).